# In the United States Court of Federal Claims

# OFFICE OF SPECIAL MASTERS No. 20-0634V UNPUBLISHED

DEBORAH PEEPLES,

Petitioner.

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: May 26, 2022

Special Processing Unit (SPU); Findings of Fact; Statutory Six Month Severity Requirement; Pneumococcal Conjugate Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Howard Scott Gold, Howard S. Gold, Sudbury, MA, for Petitioner.

Althea Walker Davis, U.S. Department of Justice, Washington, DC, for Respondent.

# FINDINGS OF FACT<sup>1</sup>

On May 21, 2020, Deborah Peeples filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>2</sup> (the "Vaccine Act"). Petitioner alleges that she suffered a right shoulder injury related to vaccine administration ("SIRVA") caused-in-fact by the pneumococcal 13-valent vaccine<sup>3</sup> she received on January 25, 2018. Petition at 1, ¶¶ 1-2, 22.

<sup>&</sup>lt;sup>1</sup> Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>&</sup>lt;sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

<sup>&</sup>lt;sup>3</sup> The pneumococcal 13-valent vaccine is a pneumococcal conjugate vaccine - routinely administered to children, and covered by the Vaccine Program. See Morrison v. Sec'y of Health & Hum. Servs., No. 04-

Because Petitioner failed to seek treatment for her SIRVA injury during a greater than 15-month period (from late May 2018 through early September 2019), Respondent questioned whether Petitioner has satisfied the statutory six-month requirement. ECF No. 24. Petitioner maintains that the symptoms she experienced in September 2019 and later reflect a continuation of her SIRVA injury. Petition at ¶ 15.

For the reasons discussed below, I find the Petitioner continued to suffer the residual effects of her alleged SIRVA for more than six months. See Section 11(c)(1)(D)(i) (statutory six-month severity requirement).

#### I. Relevant Procedural History

Within a month of filing her Petition, Ms. Peeples filed the medical records required under the Vaccine Act. Exhibits 1, 3-5, filed June 18, 2020, ECF No. 7; see Section 11(c). She also filed a declaration signed under penalty of perjury as required by 28 U.S.C.A. § 1746. Exhibit 2, ECF No. 7. On July 2, 2020, the case was activated and assigned to the Special Processing Unit (OSM's process for attempting to resolve certain, likely-to-settle claims). ECF No. 9.

No factual issues requiring further development were identified during the initial status conference held on September 24, 2020, or in Respondent's later status report. Order, issued Sept. 25, 2020, at 1, ECF No. 12; Status Report, filed Dec. 22, 2020, at 2, ECF No. 13. However, Respondent identified several medical records which appeared to be outstanding. Status Report at 1. Over the subsequent one-month period, Petitioner filed these additional medical records. Exhibits 6-7, ECF Nos. 15-16.

On July 22, 2021, Respondent filed a status report raising severity as an impediment to a favorable entitlement determination. Status Report at 1, ECF No. 24. I therefore ordered the parties to file simultaneous briefing addressing the issue. Non-pdf Order, issued July 28, 2021. Instead of briefing, however, on September 21, 2021, Petitioner filed a motion for additional time indicating that Petitioner planned to file a supplemental affidavit and the parties wanted time to discuss an informal settlement in this case. ECF No. 25. Petitioner filed a signed statement<sup>4</sup> on September 21, 2021. Exhibit 9, ECF No. 26.

<sup>1683, 2005</sup> WL 2008245, at \*1 (Fed. Cl. Spec. Mstr. July 26, 2005) (describing how and when pneumococcal conjugate vaccines were added to the Vaccine Table).

<sup>&</sup>lt;sup>4</sup> Although Petitioner refers to this statement as an affidavit, it is signed but not notarized. Additionally, it does not contain a statement indicating it was signed under penalty of perjury as required by 28 U.S.C.A. § 1746. *Id.* 

On December 2, 2021, Respondent filed a status report indicating "the parties were unable to resolve the issue regarding the severity requirement for [P]etitioner's alleged SIRVA injury." ECF No. 28. They requested that a new deadline be set for their simultaneous briefing on the issue. *Id.* 

On December 8, 2021, Petitioner filed a second signed witness statement<sup>5</sup> on her own behalf, plus a statement from one of her treating physicians – an orthopedist, Robert Dasilva, M.D., indicating that he believed her later symptoms were related to the shoulder injury she suffered in late January 2018. Exhibits 10-11, ECF No. 29. On January 20, 2022, Petitioner filed a status report requesting a fact hearing regarding the issue of severity and a copy of a late May/early June 2019 email exchange between Petitioner and Petitioner's counsel – accompanied by a declaration signed under penalty of perjury by Petitioner's counsel attesting to the email's authenticity. Status Report, ECF No. 31; Exhibit 12, ECF No. 32. On January 30 and 31, 2022, the parties filed their briefing. ECF Nos. 33-34. The matter is now ripe for adjudication.

#### II. Issue

At issue is whether Petitioner continued to suffer the residual effects of the SIRVA for more than six months. Section 11(c)(1)(D)(i) (statutory six-month severity requirement).

## III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

<sup>5</sup> This statement was (like the prior witness statement) signed but not notarized or signed under penalty of perjury as required by 28 U.S.C.A. § 1746. *Id.* 

This statement was (like the prior witness statement) signed but not notar

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at \*20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, \*4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); see also Burns v.

Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

### IV. Finding of Fact

I make this severity finding after a complete review of the record to include all medical records, statements, declarations, briefing, and additional evidence filed. Specifically, I base the findings on the following evidence:

- Petitioner received the pneumococcal 13-valent vaccine alleged as causal in her right deltoid on January 25, 2018. Exhibit 1. The same day, she also received an influenza vaccine in her opposing left deltoid. *Id.*
- On February 20, 2018, less than one-month post-vaccination, Petitioner visited her primary care provider ("PCP"), complaining of right shoulder pain and limited range of motion ("ROM"). Exhibit 6 at 1. She reported that she had soreness in both arms the day after vaccination, but "[t]he left shoulder soreness dissipated over the next few days." Id. In contrast, "the right shoulder pain intensified, and she noted pain on ROM." Id. Indicating that heating pads and cold packs had not helped, Petitioner described pain "over the lateral shoulder and deltoid area." Id. Observing pain with palpitation and at the ROM extremes, the PCP opined that Petitioner's injury "[wa]s consistent with right subacromial-subdeltoid bursitis/supraspinatus tendinitis, . . . occurred immediately after a Prevnar 13 deltoid injection, . . . [and was] presumed to occur when the needle inadvertently is place into the bursae." Id. at 2. Noting that Petitioner was currently taking Tramadol for her knee arthritis, the PCP referred her to an orthopedist and showed her how to perform exercises "to minimize the risk of frozen shoulder." Id.
- On February 23, 2018, Petitioner visited the orthopedist, reporting aching sharp pain for one month following receipt of the pneumococcal vaccine in late January 2018. Exhibit 4 at 12. Describing the same soreness in both shoulders, then improvement in the left shoulder receiving the flu vaccine and worsening in the right shoulder, Petitioner reported that the Tramadol she took for her back and knee pain was not alleviating her right shoulder pain. *Id.* Observing a painful arc but full ROM, the orthopedist ordered x-rays, administered a steroid injection, and recommended physical therapy ("PT") which Petitioner declined. *Id.* at 12-13. The orthopedist opined that

he "believe[d] the likelihood is high that this will improve with time." *Id.* at 13. The record from this visit indicates that Petitioner was a retired nurse *Id.* at 12.

- Despite the notation indicating Petitioner was declining PT (Exhibit 4 at 13), Petitioner attended four PT sessions in March 2018. Exhibit 7 at 13-25. At her first session on March 15th, she provided the same history of bilateral soreness after vaccination followed by a worsening of her right shoulder pain and reported that currently she was unable to elevate her right arm without pain. *Id.* at 21. Reporting pain levels which varied between zero and eight at her initial PT session (*id.* at 19, 21), Petitioner indicated increased soreness and pain at her next session on March 20th which she attributed to the first PT session and a Pilates class she attended the same day (*id.* at 17). At her third session, two days later, Petitioner reported a more severe level of pain seven out of ten, which started that morning. *Id.* at 15. By her fourth session on March 27, she was experiencing decreased pain but continued pain and difficulties when performing overhead tasks. *Id.* at 13.
- When she returned to her orthopedist on March 30, 2018, Petitioner expressed frustration with her slow recovery describing her pain as sharp and radiating at times. Exhibit 4 at 9-10. Reporting that she obtained only seven days relief from the steroid injection and no relief from PT, she requested the orthopedist prescribed Lidoderm patches for her pain. Observing that Petitioner had full ROM but "a painful impingement arc," the orthopedist prescribed the requested Lidoderm patches and recommended Petitioner "discontinue formal therapy because it is not helping much and switch to a home program." *Id.* at 9.
- At her last PT session on April 3, 2018, Petitioner was described as "hav[ing] pain and difficulty using her R shoulder with daily activity." Exhibit 7 at 7. The cessation of PT was attributed to Petitioner "having financial difficulty along with the slow progress and concern of adverse reaction with physical therapy." *Id.* It was noted that Petitioner had met only goals related to improved posture and less than 40 percent impairment, but Petitioner had failed to achieve less than 20 percent impairment. *Id.* at 8.
- On April 27, 2018, Petitioner underwent an MRI, the results of which included no rotator cuff tear and a trace amount of subacromial/subdeltoid bursitis. Exhibit 4 at 14-15.

- On May 4, 2018, Petitioner visited her orthopedist to discuss the results of her MRI. Exhibit 4 at 7-8. Reporting "that the shoulder pain '[wa]s getting to her," Petitioner described difficulties sleeping, bathing, and performing caretaker duties for her mother. *Id.* at 7. Noting that Petitioner had arthritic changes but no symptoms prior to vaccination, the orthopedist theorizes that "her shoulder somehow got aggravated from the injection." *Id.* He indicated that Petitioner had exhausted all conservative treatment but did not wish to pursue surgery. Instead, she preferred to "continue with her oral medications and activity modifications to manage her shoulder arthritis." *Id.*
- On May 29, 2018, Petitioner was seen by an orthopedic surgeon. Exhibit 5 at 35-37. Providing the same consistent history, Petitioner described "aching; sharp; dull, constant; [and] worsening" pain, with a current level ranging from four to eight. *Id.* at 37. After discussing options which ranged from continued conservative care to a manipulation under general anesthesia, and noting that Petitioner would be going to Florida for six to eight weeks to care for her mother, the orthopedic surgeon indicated the tentative plan was a manipulation. *Id.*
- Petitioner did not return to the orthopedic surgeon until September 10, 2019 over fifteen months from the date of her last 2018 treatment visit. Exhibit 5 at 32-35. However, in response to an email inquiry by Petitioner's counsel approximately three months earlier, Petitioner had reported that she continued to experience symptoms of her shoulder injury throughout the gap in treatment. Exhibit 12 at 3 (Counsel's May 31, 2019 email and Petitioner's June 3, 2019 response). Noting the length of time that had passed, she recalled that one of her physicians (thought to be her PCP) told her "it could take that long to recover." *Id.* Attributing her delay in treatment to her reluctance to undergo surgery, Petitioner indicated that she planned to seek a current assessment from the orthopedic surgeon in late July/early August, and to pursue a surgical option. *Id.* It appears Petitioner called to schedule the September 10 appointment on August 13, 2019. Exhibit 5 at 32.
- At the September 10, 2019 appointment, the orthopedic surgeon assessed Petitioner as "continu[ing] to have pain in the shoulder really without much improvement." Exhibit 5 at 34. He recommended arthroscopic surgery, and Petitioner agreed. *Id.*

- During the October 2, 2019 surgery, it was revealed that Petitioner suffered from "[s]ignificant arthritis" and "a small partial thickness rotator cuff." Exhibit 5 at 32. In the clinical history section, Petitioner is described as having "continued shoulder pain despite conservative care." *Id.*
- After surgery, Petitioner began PT on October 9, 2019. Exhibit 5 at 24-27. There is evidence that Petitioner may have aggravated her right shoulder condition on in November 2019, which resulted in an increase in her pain. *Id.* at 8. Additionally, she may have suffered an unrelated injury in the fall of 2020 when reaching out to put a dog in a kennel. Exhibit 8 at 10. Petitioner recalled feeling a pop in her shoulder at that time. *Id.*
- In a December 6, 2021 letter, Petitioner's orthopedic surgeon opined that the right shoulder pain Petitioner experienced in September 2019 was a continuation of the pain she suffered in May 2018. Exhibit 11.
- In her most recent signed statement, Petitioner avers that her "decision to delay surgery until October 2019 was a result of financial constraints, family obligations, [her] desire to avoid surgery, and most importantly exhausting more conservative care including steroid injections, exercises and time." Exhibit 10 at ¶ 10. Petitioner specifically reported that, given a \$45 co-pay for each PT session, the monthly cost of her pre-surgery PT would have been almost \$400. Id. at ¶¶ 7-8.

In this case, to satisfy the Vaccine Act's severity requirement Petitioner must show that she suffered symptoms of her alleged SIRVA beyond July 25, 2018. Thus, Petitioner must establish that the symptoms she complained of in September 2019 were a continuation of her 2018 SIRVA injury - or that, at a minimum, that the symptoms she reported in May 2018 continued through at least until July 25<sup>th</sup> of the same year.

The above medical entries show that Petitioner was clearly experiencing symptoms of her alleged right shoulder injury in late May 2018, approximately four months post-vaccination. And they underscore the extent to which she obtained little relief from the conservative treatment she received during that time. The cortisone injection administered in late February provided only seven days of relief, and the PT sessions in March and early April appeared to aggravate, rather than relieve, Petitioner's symptoms. At the last orthopedic appointment on May 27, 2018 (just before the start of the lengthy treatment gap), Petitioner described her continuing symptoms and expressed her desire to undergo a manipulation under general anesthesia after an extended trip to Florida to care for her mother. Given the constant nature of Petitioner's symptoms from vaccination

through late May 2018, and the lack of relief she obtained from the conservative treatment she pursued, it highly likely that her symptoms continued at least through the end of July 2018.

My conclusion is bolstered by the symptoms Petitioner reported in September 2019, which reasonably appear to relate to those she experienced in 2018. The medical records contain evidence which clearly supports the reasons Petitioner provided for the 15-month gap in treatment - financial constraints, family concerns, and a reluctance to undergo surgery. And it is reasonable for Petitioner, a retired nurse, to attempt to treat herself with conservative measures before undergoing surgery. Petitioner stated that she was informed, by at least one treating physician, that it could take at least 18 months for her injury to resolve.

Most compelling is the opinion of the orthopedic surgeon, who saw Petitioner just prior to and following this gap in treatment. He has opined that the later symptoms were a continuation of Petitioner's earlier injury. And the symptoms Petitioner complained of in 2019 mirrored those she reported in 2018.

The overall record in this case shows that the right shoulder pain and limited ROM Petitioner complained of following her January 25, 2018 vaccination continued at least through her October 2019 surgery and early post-surgical PT. Accordingly, I find there is preponderant evidence to establish Petitioner suffered the residual effects of her alleged SIRVA for more than six months. Of course, the lengthy gap in treatment is highly relevant to damages, as it not only supports the conclusion that Petitioner's SIRVA was mild enough to tolerate for a long period, but also that intervening circumstances could explain some degree of severity thereafter. But this does *not* mean I cannot find the basic requirement of six months severity met. A treatment gap that includes within it the "expiration date" for severity does not automatically mean severity cannot be established.

# V. Later Sequelae and Scheduling Order

As stated in the previous section, there is evidence indicating that Petitioner may have aggravated her right shoulder condition in November 2019, and may have suffered an unrelated injury in the fall of 2020. However, these matters are relevant when determining the appropriate amount of compensation, as noted above. I need not address their connection to Petitioner's earlier condition when determining whether Petitioner has satisfied the severity requirement.

In light of my finding regarding the Vaccine Act's severity requirement, Respondent should consider his tentative position in this case. **Respondent shall file a status report** 

indicating how he intends to proceed following my ruling by no later than <u>Monday</u>, <u>June 27, 2022</u>.

IT IS SO ORDERED.

s/Brian H. CorcoranBrian H. CorcoranChief Special Master